FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Meeting of the Oncologic Drugs Advisory Committee (ODAC)

FDA White Oak Campus, Building 31, the Great Room (Rm. 1503) White Oak Conference Center, Silver Spring, Maryland January 7, 2015

MEETING ROSTER

DESIGNATED FEDERAL OFFICER (Non-Voting)

Caleb Briggs, PharmD

Division of Advisory Committee and Consultant Management Office of Executive Programs, CDER, FDA

ONCOLOGIC DRUGS ADVISORY COMMITTEE MEMBERS (Voting)

Deborah K. Armstrong, MD (Chairperson) James I

Professor of Oncology
The Sidney Kimmel Comprehensive Cancer Center

at Johns Hopkins
The Johns Hopkins University School of Medicine

Baltimore, Maryland

Bernard F. Cole, PhD

Professor, Department of Mathematics and Statistics University of Vermont Burlington, Vermont

Tito Fojo, MD, PhD

Senior Investigator Director, Medical Oncology Fellowship Program Medical Oncology Branch, Center for Cancer Research National Cancer Institute, National Institutes of Health

Bethesda, Maryland

James Liebmann, MD

Assistant Professor of Medicine Department of Medicine University of Massachusetts Worcester, Massachusetts

Bruce J. Roth, MD

Professor of Medicine Division of Oncology Washington University School of Medicine St. Louis, Missouri

<u>Jane Zones, PhD</u> (Consumer Representative)

Medical Sociologist (retired) Member, Former Board Member Breast Cancer Action National Women's Health Network San Francisco, California

ONCOLOGIC DRUGS ADVISORY COMMITTEE MEMBER (Non-Voting)

<u>Howard Fingert, MD, FACP</u> (*Industry Representative*)

Senior Medical Director, Clinical Intelligence Millennium, the Takeda Oncology Company Cambridge, Massachusetts

FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Meeting of the Oncologic Drugs Advisory Committee (ODAC) January 7, 2015

MEETING ROSTER (cont.)

TEMPORARY MEMBERS (Voting)

William I. Bensinger, MD

Professor of Medicine Division of Oncology University of Washington Seattle, Washington

Randy Hillard, MD (Patient Representative)

East Lansing, Michigan

Ginna G. Laport, MD

Professor of Medicine Division of Blood and Marrow Transplantation Stanford University Medical Center Stanford, California

Donald E. Mager, PharmD, PhD

Associate Professor of Pharmaceutical Sciences Department of Pharmaceutical Sciences University at Buffalo, State University of New York Buffalo, New York

Antonio R. Moreira, PhD

Vice Provost for Academic Affairs Professor, Department of Chemical, Biochemical and Environmental Engineering University of Maryland, Baltimore County Baltimore, Maryland

Kathleen Neville, MD, MS

Associate Professor of Pediatrics
Director, Experimental Therapeutics in Pediatric
Cancer
Children's Mercy Hospitals and Clinics
Divisions of Pediatric Hematology/Oncology
and Pediatric Pharmacology and Medical Toxicology
Kansas City, Missouri

David F. Stroncek, MD

Senior Clinician Chief, Cell Processing Section Department of Transfusion Medicine Clinical Center, National Institutes of Health Bethesda, Maryland

Scott A. Waldman, MD, PhD, FCP, FAHA Samuel M.V. Hamilton Professor and Chair

Department of Pharmacology and Experimental Therapeutics Sidney Kimmel Medical College Thomas Jefferson University Philadelphia, Pennsylvania

FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Meeting of the Oncologic Drugs Advisory Committee (ODAC) January 7, 2015

MEETING ROSTER (cont.)

FDA PARTICIPANTS (Non-Voting)

Steven Kozlowski, MD

Director Office of Biotechnology Products (OBP) Office of Pharmaceutical Quality (OPQ) CDER, FDA

John Jenkins, MD

Director Office of New Drugs (OND) CDER, FDA

Leah Christl, PhD

Associate Director for Therapeutic Biologics Therapeutic Biologics and Biosimilars Team (TBBT) OND, CDER, FDA

Richard Pazdur, MD

Director Office of Hematology & Oncology Products (OHOP) OND, CDER, FDA

Edvardas Kaminskas, MD

Deputy Director Division of Hematology Products (DHP) OHOP, OND, CDER, FDA